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discussed the Species Election Requirement set forth in Paper No. 7, as detailed below. Applicant's undersigned representative explained that contrary to the Examiner's assertion in Paper No. 7, the patentably distinct species covered by Applicant's Specification and embodied in generic claims 11 and 21, do indeed possess a "common central core or significant structural element". The Examiner agreed and indicated that she would reconsider the Requirement upon traversal. Applicants' undersigned representative agreed that such "common central core or significant structural elements" would be noted in the instant response.

#### Species Election Requirement

As set forth in Paper No. 7, the Examiner has required the election of a single disclosed species for prosecution on the merits. The Examiner contends that the application contains claims directed to several patentably distinct species of hypocholesteremic preparations comprising phytosterol compounds and conjugated fatty acids. (Paper No. 7, p. 2). The Examiner argues that the identified species lack unity of invention "because they are not so linked as to form a single general inventive concept under PCT Rule 13.1." (*Id.*). The Examiner has identified the species of phytosterol compounds as "(a) phytosterols and phytosterol esters, (b) sitosterol and sitosterol esters, (c) sitostanol and sitostanol esters," and has identified the species of conjugated fatty acids as (a) the acids *per se*, and (b) glycerides thereof. The Examiner argues that these species lack the same or corresponding special technical features under PCT Rule 13.2, because "compounds useful in the claimed product and method of use . . . vary greatly in chemical structure and lack any common central core or significant structural element." (Paper No. 7, p. 3). However, the Examiner acknowledges that all pending claims, 11-30, are generic to all disclosed species. On the basis of the foregoing arguments and contentions, the Examiner argues that a search covering all species presents an undue burden on the Examiner.

#### Traversal of the Restriction Requirement

Applicant strenuously, but respectfully, traverses the species election requirement for the following reasons.

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To begin with, as the Examiner has noted, Unity of Invention practice applies in the instant application which is a national stage U.S. application based upon an International application. Section 1893.03(d) of the M.P.E.P., 7<sup>th</sup> Edition, Revision 1, clearly explains 37 C.F.R. §1.499, which concerns Unity of Invention during the national stage, as follows: "[w]hen making a lack of unity of invention requirement, the examiner must (1) list the different groups of claims and (2) explain why each group lacks unity with each other group (*i.e.*, why there is no single general inventive concept) specifically describing the unique special technical feature in each group." (M.P.E.P. §1893.03(d), (*emphasis added*)). While the Examiner does not identify specific groups of claims, nor specifically describe the unique special technical feature of each species, the Examiner contends that the identified species "vary greatly in chemical structure and lack any common central core or significant structural element." (Paper No. 7, p. 3 (*emphasis added*)). Applicant respectfully submits that the Examiner is incorrect in this regard.

Applicant's claimed invention is directed to a method of reducing serum cholesterol content in a mammal, said method comprising: (i) providing a hypocholesteremic preparation comprising at least one component (a) selected from the group consisting of phytosterols and phytosterol esters and at least one component (b) selected from conjugated fatty acids having from about 6 to about 24 carbon atoms and glycerides of conjugated fatty acids having from about 6 to about 24 carbon atoms; and (ii) administering the hypocholesteremic preparation to a mammal in an amount effective to reduce serum cholesterol content in the mammal.

The species of component (a), as identified by the Examiner, are plant-steroidal alcohols, hydrogenated forms thereof or ester derivatives thereof, as indicated by the term phytosterol, "phyto" referring to plants, and as explained in the Specification at page 2, line 33, through page 4, line 4. Moreover, the species identified by the Examiner as (i)(b) and (i)(c) are specific types of the compounds identified as species (i)(a). Thus, the alleged "species" (i)(a) actually encompasses species (i)(b) and (i)(c). At any rate, all of these compounds are related and most certainly possess a "common central core or significant structural element". Specifically, all phytosterol compounds in accordance with Applicant's claimed invention possess a fused, tetracyclic, steroidal nucleus with a hydroxyl functionality at the C-3 carbon position. Phytosterol esters in accordance with the claimed invention have had the hydroxyl functionality replaced with an ester linkage, but retain the core steroidal nucleus. Hydrogenated

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derivatives have had one or more double bonds saturated, but retain the fused, tetracyclic nucleus. Thus, Applicant respectfully submits that all phytostenols and phytostenol esters possess a "common central core or significant structural element".

The species of component (b), as identified by the Examiner, all contain conjugated fatty acids. The conjugated fatty acids may be in their free acid form, or as commonly encountered in nature, as glycerides. In either instance, a component (b) will possess conjugated double bonds, regardless of whether the conjugated chain is attached to glycerol as an ester or freely existing as a fatty acid. Thus, Applicant respectfully submits that conjugated fatty acids and glycerides of conjugated fatty acids possess a "common central core or significant structural element".

Furthermore, phytostenol compounds are often found in nature as complex mixtures of several specific phytosterols, phytosterol esters, phytostanols, and phytostanol esters. For example, it is common to find plant extracts which contain  $\beta$ -sitosterol,  $\beta$ -sitostanol, and a variety of esters of each, in varying amounts. As indicated at page 3, lines 8-9, in one preferred embodiment of the invention, mixtures of phytostenols and phytostenol esters are used. Thus, election of a particular, single phytostenol compound would preclude election of a preferred embodiment.

It is respectfully submitted that an examination on the merits of all disclosed species would not present an undue burden on the Office or the Examiner. A reasonable novelty search of hypocholesteremic preparations containing sterols and/or stanols and/or their derivatives is likely to cover the subject matter of most or all of the disclosed species.

Therefore, Applicant respectfully submits that the election requirement of a single disclosed species for prosecution on the merits is improper, and further request reconsideration by the Examiner, withdrawal of the election requirement, and concurrent prosecution on the merits of all species claimed.

**Provisional Election With Traverse**

In the event the Examiner does not find Applicant's arguments with respect to the withdrawal of the election requirement persuasive, and the Examiner maintains the election requirement set forth in Paper No. 7, Applicant provisionally elects the species identified by the Examiner as hypocholesteremic preparations comprising: (i)(a) "phytostenols and phytostenol

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esters"; and (ii)(a) "conjugated fatty acids having about 6 to about 24 carbon atoms", as embodied in claims 11-30, with traverse, for prosecution on the merits. Furthermore, Applicant respectfully submits that claims 11-30 read on the provisionally elected species, and that claims 11 and 21 are generic to all species.

Respectfully submitted,

**BERND FABRY**

January 8, 2001  
(Date)

By: \_\_\_\_\_

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